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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,202	11/12/2003	Randall J. Huebner	ACM 352	8269
23581	7590	05/01/2007		
KOLISCH HARTWELL, P.C. 200 PACIFIC BUILDING 520 SW YAMHILL STREET PORTLAND, OR 97204			EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 05/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/712,202

Applicant(s)

HUEBNER ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-9,11,13-15,17-26,28 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-9,11,13-15,17-26,28 and 31-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-9, 11, 13-15, 17-19, 21-25, 35-38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Lombardo (US Pub. 2001/0001119 A1).

Lombardo discloses a bone screw for compression of a bone comprising a shank (Fig. 4, shank of ref. 15) including a thread (Fig. 4, ref. 15) disposed externally for threaded engagement with bone, the shank defining a long axis (Fig. 4) and a direction of advancement into bone (Fig. 4, from ref. 1 towards ref. 15); and a head (Fig. 2, ref. 24) connected to the shank and defining a plurality of ledge structures (Fig. 2, ref. 14) disposed at spaced positions along the head (Fig. 2), each ledge structure facing generally toward the direction of advancement (Fig. 2) and extending partially or completely around the head to define a respective plane disposed orthogonally to the long axis (Fig. 2). The shank has a proximal portion (Fig. 2, portion near ref. 14) adjacent the head and a distal portion (Fig. 2, portion near ref. 15) spaced from the head, and wherein the thread is restricted to the distal portion (Fig. 2). The bone screw is self-tapping (Fig. 2). The shank includes a tip region (Fig. 2, tip at end of shaft, below ref. 15) configured to cut a hole in the bone as the bone screw is advanced into the bone. The ledge structures are formed by a plurality of ridges (Fig. 2, ref. 14), a plurality

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of grooves, or both. One or more of the plurality of ledge structures extend in a closed loop corresponding to a circle (Fig. 2). The plurality of ledge structures have a corresponding plurality of diameters, and wherein the diameters decrease successively toward the shank (Fig. 2). The head is shaped generally as a frustum of a cone (Fig. 2). The head includes a plurality of steps defined by stepwise decreases in the diameter of the head (Fig. 2), and wherein the plurality of ledge structures are included in the plurality of steps (Fig. 2). The shank and the head define opposing ends of the bone screw (Fig. 2, the opposite ends of the bone screw) and further define an axial bore (Fig. 2, ref. 10) extending between the opposing ends. The axial bore includes a widened region (Fig. 2, ref. 10, widest portion near the top of ref. 10) configured to receive a tool that engages the head. The head and the shank are both part of the same monolithic structure (Fig. 2).

Lombardo discloses a bone screw for compression of a bone, comprising: a shank (Fig. 2, shank of ref. 15) including a proximal region (Fig. 2, region near ref. 1), a distal region (Fig. 2, region near ref. 15), and a thread (Fig. 2, ref. 15) disposed externally for threaded engagement with bone and restricted to the distal region (Fig. 2); and a head (Fig. 2, ref. 24) connected to the shank and spaced from the thread by the proximal region, the head defining a plurality of spaced ledge structures (Fig. 2, ref. 14) disposed along the head, each ledge structure extending in a respective plane to describe at least an arc of a circle (Fig. 2). The ledge structures are defined by a plurality of ridges (Fig. 2, ref. 14), a plurality of grooves, or both. The ledge structures describe complete circles (Fig. 2). The head includes a plurality of steps defined by

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stepwise decreases in the diameter of the head (Fig. 2), and wherein the plurality of ledge structures are included in the plurality of steps (Fig. 2). The head is generally frustoconical in shape (Fig. 2). The shank defines a long axis (Fig. 2), wherein the head has a maximum diameter (Fig. 2), wherein the head has an axial length that is measured parallel to the long axis (Fig. 2). The head has an aspect ratio defined by the axial length of the head relative to the maximum diameter of the head (Fig. 2).

Lombardo discloses a bone screw for compression of a bone comprising a shank (Fig. 2, shank of ref. 15) including a thread (Fig. 2, ref. 15) disposed externally for threaded engagement with bone, the shank defining a long axis (Fig. 2) and a direction of advancement into bone (Fig. 2) and a head (Fig. 2, ref. 24) connected to the shank and including a plurality of spaced shoulders (Fig. 2, ref. 14) of different diameter, each shoulder facing generally in the direction of advancement and extending partially or completely around the long axis in a respective path defining a plane (Fig. 2). Each shoulder follows a respective path defining a plane oriented orthogonally to the long axis (Fig. 2). Each shoulder follows a respective path corresponding to at least an arc of a circle (Fig. 2). Each shoulder extends completely around the long axis in a closed loop (Fig. 2). The head includes at least one generally cylindrical segment (Fig. 2, ref. 14) disposed at least partially between a pair of the shoulders, since one of shoulders which is located centrally relative to the other shoulders can be considered to be a cylindrical segment.

Claims 28 and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Lichty (US Pat. 4,456,005).

Lichty discloses a method of compressing a bone with a bone screw comprising: forming a hole in the bone (Fig. 2, hole near ref. 10); selecting a bone screw (Fig. 1) having a shank (Fig. 1, ref. 16) and a head (Fig. 1, ref. 22) connected to the shank, the head defining a plurality of ledge structures (Fig. 1, refs. 14) (Fig. 4) disposed at spaced positions along the head (since the ledge structures are placed onto the head at different times as the method is carried out, column 3, lines 13-18), each ledge structure facing generally toward the direction of advancement (Fig. 4) and extending partially or completely around the head (Fig. 4) to define a respective plane disposed orthogonally to the long axis (Fig. 4) and advancing first the shank and then the head of the bone screw into the hole via threaded engagement of the shank with bone (Fig. 2), such that a portion of the bone near the head is compressed toward a portion of the bone near the shank (Figs. 3-4). The step of forming a hole includes a step of forming a bore (Fig. 2, lower bore with ref. 16 inside) and a counterbore (Fig. 2, upper bore with ref. 10 inside), and wherein the step of advancing disposes the head and the shank at least substantially in the counterbore and the bore, respectively (Fig. 4). The step of forming a hole is performed by the step of advancing, since the hole that is drilled is smaller than the threads of the screw, therefore a hole must be made by the screw as it is screwed into the bone (column 2, lines 55-68 and column 3, lines 1-4). The portion near of the bone near the head and the portion of the bone near the shank are initially separated by a fracture in the bone (Fig. 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lombardo (US Pub. 2001/0001119 A1).

Lombardo discloses the claimed invention except for the aspect ratio being at least 1:1.

With regard to claim 26, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the aspect ratio of the device of Lombardo as being at least 1:1, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 34 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lombardo (US Pub. 2001/0001119 A1) in view of Lahille et al. (US Pat. 5,743,912).

Lombardo discloses the claimed invention except for each shoulder sloping radially outward, generally toward the direction of advancement into bone.

Lahille et al. discloses shoulders which slope radially outward (Fig. 5, ref. 14). This prevents the device from recoiling back out of the hole in which it is placed (column 5, lines 32-35).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the shoulders of Lombardo with the radial outward slope as taught by Lahille et al., in order to prevent the device of Lombardo from recoiling back out of the hole in which it is placed (Lahille et al., column 5, lines 32-35).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lombardo (US Pub. 2001/0001119 A1) in view of Schenk (US Pat. 6,048,344).

Lombardo discloses the claimed invention except for the head being rotatably and/or slidably connected to the shank.

Schenk discloses a device used in the compression of bone fragments (Fig. 8, column 1, lines 8-12) which comprises a head (Fig. 4, ref. 1) which is slidably connected (Figs. 7 and 8) to a shank (Fig 4, ref. 60). This arrangement allows the head to provide improved compressive forces while permitting the bone screw head to be located beneath the bone surface (abstract).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the bone of bone screw of Lombardo with a head which is slidably connected to a shank as taught by Schenk, in order to allow the

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head of Lombardo to provide improved compressive forces while permitting the bone screw head to be located beneath the bone surface (Schenk, abstract).

Response to Arguments

Applicant's arguments with respect to claims 5-9, 11, 13-15, 17-26, 28 and 31-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER